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April 28, 2000

FDA/Dockets Management Branch (HFA-305)
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. 00N-0352
Status of Useful Written Prescription Drug Information for Patients; Public Meeting
65 Fed. Reg. 7022 (February 11, 2000)

Dear Sir or Madam:

AARP appreciates this opportunity to comment on proposed methods to determine whether the written prescription drug information currently being provided voluntarily to patients meets the guidelines set out in the "Action Plan for the Provision of Useful Prescription Medicine Information" (Action Plan).

Older persons represent a substantial portion of users of prescription medicines, which play an every-increasing role in health care. While prescription medicines provide tremendous benefits, there are still far too many incidents of serious adverse side effects associated with them. At the same time, there is also an alarmingly high number of patients who do not follow their prescription medicine regimes. AARP continues to believe that both of these problems can be addressed by providing patients with "useful" written information about their prescription medicines at the time they receive their medicines. For this reason, AARP strongly supported FDA's original "medication guide" proposal, and participated in the development of the Action Plan, which established voluntary guidelines for what constitutes "useful" information.

The Action Plan has been in place since 1997, and FDA has begun the process of determining how best to evaluate compliance with it. The legislation authorizing the Action Plan requires that 75 percent of all new prescriptions by the year 2000 be distributed with useful written information. As part of its responsibility for assessing compliance with the Action Plan, FDA commissioned an interim study that developed a methodology for evaluating existing written information about prescription medicine. We have reviewed the methodology and findings of the interim study and we participated in the recent public meeting on it. We would like to focus our comments on four of the questions asked by FDA in the February 11, 2000 notice announcing the public meeting:

00N-0352

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1. What should be the minimum standard or threshold that must be met for written information to be considered useful?

AARP strongly urges FDA to make the standard for compliance with the voluntary guidelines as close to full compliance as is practicable. We do not support an evaluation approach that would "count" partial compliance with the guidelines towards the 75-percent goal. AARP has long supported mandatory requirements for the provision of written information about prescription medicines because we believe that only a mandatory program would ensure widespread availability of useful information. AARP participated in the development of voluntary guidelines when this approach became the only one that was politically feasible. We worked diligently to ensure that the guidelines for both the form and content of the written information were sufficiently specific to ensure that most patients would receive the information they need. To start out with a mandatory program for written prescription medicine information and end up with one that *only* calls for the provision of written prescription information that *partially* complies with the voluntary guidelines (in *only 75 percent* of new prescriptions issued in the year 2000) falls far short of the goal of significantly improving public health.

AARP believes that full compliance with the voluntary guidelines is required by the authorizing legislation. Public Law 104-180 establishes as its goals the distribution of useful written information to 75 percent of individuals receiving new prescriptions by the year 2000, and 95 percent by the year 2006. While the statute does indicate that the plan for providing voluntary guidelines must include a mechanism to assess periodically the quality of the information and the frequency with which the information is provided to consumers, the law gives no further guidance on what constitutes "sufficient" compliance. Absent specific statutory language characterizing the required level of compliance, FDA should conclude that written prescription information products must fully comply with the guidelines in order to "count" towards the goal. Moreover, to the degree that FDA has the discretion to decide what level of compliance should be required, it should select the level of compliance most protective of consumers.

By contrast, the language of Public Law 101-535, the Nutrition Labeling and Education Act (NLEA), contains specific qualifying language regarding compliance. That statute requires FDA to develop voluntary guidelines for the provision of nutrition information about raw fruits, vegetables, and fish and to define "*substantial* compliance" with these guidelines. The NLEA further provides that there is no "substantial compliance" if "a *significant* number of retailers have failed to comply with the guidelines." It is reasonable to conclude, therefore, that if Congress had wanted there to be less than full compliance with the voluntary guidelines for written prescription information, then it would have so indicated in the authorizing legislation.

2. Should there be a more detailed assessment of factors affecting readability and legibility for consumers (e.g., type size, style, spacing, and contrast)?

AARP urges FDA to undertake a more detailed assessment of factors affecting readability and legibility of written prescription information. This was the recommendation of the expert panel involved in the interim study and the view of many of the participants at the public meeting on February 29, 2000. AARP has long advocated specific format standards for written materials, whether they be medicare forms, food and drug labels, or written information about prescription medicines. Comprehensive requirements for the content of written information are meaningless unless that written information is presented in a manner that allows those persons with impaired vision (in large part older adults) to read it. AARP was instrumental in the development of the format guidelines contained in the Action Plan (pages 23-24 and Appendix G) and we believe that following these guidelines best ensures that written information is readable and legible.

We also recommend that FDA include in its evaluation of written materials an assessment of the reading levels of written prescription information currently available. The Action Plan specifically recommends that prescription medicine information be written at the sixth-through eighth-grade reading level. By so doing, it is more likely that those patients who could benefit most from the information – those who have low literacy levels and do not have regular access to health care professionals – actually receive information that they can use.

3. Should the evaluation panel include consumers with varying educational backgrounds? If so, how should they be involved in the evaluation process?

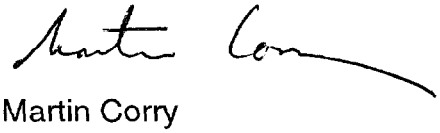
FDA's assessment of the written prescription information currently available in the marketplace must include an evaluation of the materials by actual consumers and not just "experts." Because these materials are being developed for patients, not health professionals, some sort of formal assessment by consumers of an appropriate sample of materials – whether through focus groups or some other method – is absolutely essential. Moreover, we would urge FDA to include in this consumer evaluation both older persons and those with low literacy skills, two groups that would particularly benefit from written prescription medicine information.

4. Are there ways to expand sampling to include mail-order or other nonretail pharmacies?

AARP recommends that FDA include in its assessment of written prescription information those materials provided by mail-order pharmacies, because these vendors, which constitute approximately 12 percent of the market, provide medicines to a significant portion of the population. By contrast, materials provided by on-line pharmacies (that are not associated with mail-order pharmacies) should not be included because they currently comprise less than one-half of one percent of the market.

We appreciate this opportunity to comment on this proposal. If you have any additional questions, please contact Mila Becker (202-434-3770) of our Federal Affairs Staff.

Sincerely,



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URGENT!